

# UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	TA	TORNEY DOCKET NO.
		一 [	EX	AMINER
			ART UNIT	PAPER NUMBER
		_		16
			DATE MAILED:	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

## Office Action Summary

Application No.

Applicant(s)

09/266,935

Examiner

Jezia Riley

Group Art Unit 1656

Li et al.

X Respo	onsive to communication(s) filed on Nov 6, 2000	•	
This a	action is FINAL.		
	this application is in condition for allowance except for cordance with the practice under Ex parte Quayle, 1935		
is longer, application	ned statutory period for response to this action is set to from the mailing date of this communication. Failure to become abandoned. (35 U.S.C. § 133). Extension 1.136(a).	o respond within the period for response will cause the	
Dispositi	on of Claims		
X CI	aim(s) <u>30-54</u>	is/are pending in the application.	
Ot	f the above, claim(s)	is/are withdrawn from consideration	
CI	aim(s)	is/are allowed.	
X CI	aim(s) 30-54	is/are rejected.	
CI	aim(s)	is/are objected to.	
Cl	Claims are subject to restriction or election requirem		
Th Th Tr Priority t At	is/are objected to by the Examiner.  The oath or declaration is objected to by the Examiner.	is approved disapproved.  under 35 U.S.C. § 119(a)-(d).  the priority documents have been  ber)  International Bureau (PCT Rule 17.2(a)).	
A	cknowledgement is made of a claim for domestic priority	y under 35 U.S.C. § 119(e).	
☐ In	tent(s) otice of References Cited, PTO-892 formation Disclosure Statement(s), PTO-1449, Paper Noterview Summary, PTO-413 otice of Draftsperson's Patent Drawing Review, PTO-94 otice of Informal Patent Application, PTO-152		

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### DETAILED ACTION

#### Response to Remarks

- 1. Applicants' arguments and amendments, filed on 11/6/00, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.
- 2. This action contains newly applied rejections and/or objections. Therefore, applicants are hereby informed that the finality of the previous office action, mailed 8/9/00, has been withdrawn, and that prosecution has been reopened.

#### Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

4. Claims 30-46 are rejected under 35 U.S.C. § 101, because they are directed to non-statutory subject matter. The claims are directed to a "composition", which as recited, does not appear to differ from the naturally occurring composition in a cell. It is suggested that the claim recite a "purified" or "isolated"

composition, or some similar recitation which might be enabled by the specification.

## Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 30-45, 50-54 are rejected under 35 U.S.C. \$ 112,  $2^{10}$  paragraph.

Claim 30 is vague and indefinite because it is unclear why the applicants have not written the formula I to include A and X. It is suggested to rewrite the formula to include A and X to avoid confusion and complication.

Claims 35-39, 41, 43, and 44 are vague and indefinite because it is unclear, of what are the metes and bonds of the terms "derivatives thereof".

## Claim Rejections - 35 USC \$ 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 30-54 are rejected under 35 U.S.C. § 102(a) as being anticipated by Frackman et al. (Materials and Methods (Promega Notes pages 27-29, February 1998).

Frackman et al. Discloses Betaine and DMSO, two PCR enhancing agents. Such agents can be included in PCR amplifications to increase yield, specificity, and consistency.

9. Claims 30-54 are rejected under 35 U.S.C. § 102(a) as being anticipated by Henke et al. Nucleic acids Research, Vol. 25, 1997, pp 3957-3958).

Henke et al. Disclose Betaine which improves co-amplification. The inclusion of betaine improves the amplification and is effective with conventional polymerases.

10. Claims 30-54 are rejected under 35 U.S.C. § 102(a) as being anticipated by Hengen (TIBS 22, 1997, pp. 225-226).

Hengen discloses the use of betaine in amplification assays. Not only high GC containing targets are more easily amplified but that improvements are also seen in the amount of product.

11. Claims 30-54 are rejected under 35 U.S.C. § 102(a) as being anticipated by Frackman et al. (Materials and Methods (Promega Notes pages 27-29, February 1998).

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Frackman et al. Discloses Betaine and DMSO, two PCR enhancing agents. Such agents can be included in PCR amplifications to increase yield, specificity, and consistency.

12. Claims 30-37, 42-51 are rejected under 35 U.S.C. § 102(b) as being anticipated by Joung et al. (Journal of Virology, Oct. 1992, pp. 5788-5796).

Joung discloses DNA polymerase assays comprising DNA polymerase activity in the presence of Ad DBP for example, (see page 5790, col. 2).

- 13. No claim is allowed.
- 14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is (703) 305-6855. The Examiner may normally be reached Monday through Friday, 0900 1700 EST. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Margaret Parr, may be reached at (703) 308-2454.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix Receptionist whose telephone number is (703) 308-0196.

Any necessary fax can be sent to (703) 308-4242.

PRIMARY EXAMINER